K103551

MAR 25 2011

5. 510(k) SUMMARY

January 12, 2010

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Senior Manager, Global Regulatory Affairs
1620 Waukegan Rd. MPGR-AL
McGaw Park, IL 60085
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DEVICE NAME:

Trade name:
Intravenous Extension Tubing Kits

Table 5-1.
Product Codes for Intravenous Extension Tubing Kits

Code number	Name
2N8220	Clearlink System Non-DEHP Catheter Extension Set Kit, 7.7"(20.0 cm), Vol. 1.10 ml
2N8221	Interlink System Non-DEHP Catheter Extension Set Kit, 7.1"(18.0 cm), Vol. 0.85 ml
2N8222	Clearlink System Non-DEHP Catheter Extension Set Kit, 8.2"(21.0 cm), Vol. 0.57 ml
2N8223	Interlink System Non-DEHP Catheter Extension Set Kit, 7.7"(19.45 cm), Vol. 0.22 ml
2N8224	Clearlink System Non-DEHP Y-Type Catheter Extension Set Kit, 6.5"(16.45 cm), Vol. 1.2 ml
2N8225	Interlink System Non-DEHP Y-Type Catheter Extension Set Kit, 5.3"(13.4 cm), Vol. 1.21 ml
2N8227	Interlink System Non-DEHP Y-Type Catheter Extension Set Kit, 5.5"(13.9 cm), Vol. 0.85 ml
6N8220	V-Link Luer Activated Device with VitalShield Protective Coating Non-DEHP Catheter Extension Set Kit, 7.6"(19.3 cm), Vol. 1.0 ml

Table 5-1.
Product Codes for Intravenous Extension Tubing Kits

Code number	Name
6N8222	V-Link Luer Activated Device with VitalShield Protective Coating Non-DEHP Catheter Extension Set Kit, 8.2"(21.0 cm), Vol. 0.5 ml
6N8224	V-Link Luer Activated Device with VitalShield Protective Coating Non-DEHP Y-Type Catheter Extension Set Kit, 5.3"(13.5 cm), Vol. 1.2 ml

Common name: Intravenous Extension Tubing Kits

Classification name: IV Administration Set (21 CFR 880.5440, Product Code FPA), Intravenous Extension Tubing Set (21 CFR 880.5440, Product Code OJA), Intravascular Catheter Securement Device (21 CFR 880.5210, Product Code KMK), Bandage, Liquid, Skin Protectant (21 CFR 880.5090, Product Code NEC).

PREDICATE DEVICES:

Table 5-2.
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance date
APLICARE Skin Protectant Prep Pad	APLICARE, Inc.	K861557	July 11, 1986
Modified Interlink Injection Site Septum	Baxter Healthcare	K925126	July 18, 1993
Modification to Solution Administration Set with Capped Luer Activated Device (Clearlink).	Baxter Healthcare	K003225	October 19, 2000
CLEARLINK Antimicrobial Luer Activated Device and Extension Sets with CLEARLINK Antimicrobial Luer Activated Device	Baxter Healthcare	K072576	November 6, 2007
V-LINK Antimicrobial Luer Activated Device and Extension Sets with V-LINK Antimicrobial Luer Activated Device	Baxter Healthcare	K081289	August 4, 2008

DESCRIPTION OF THE DEVICE:

The intravenous extension tubing kits will consist of an intravenous extension tubing set, a Vital-Hold catheter stabilization device, two foam tape strips and an APLICARE skin protectant prep pad. The intravenous extension sets may contain any of Baxter's cleared access ports (e.g., Interlink Injection Site, Clearlink Luer Activated Valve or V-Link Luer Activated Valve).

The IV extension tubing set is used with a vascular access device for administration and withdrawal of fluids.

The Vital-Hold catheter stabilization device is used to help anchor medical intravenous tubes and lines requiring mechanical stability while installed on the skin surface of a patient.

The two foam tape strips with release liners are used to assist with line stabilization.

The APLICARE skin protectant prep pad is a sterile pad saturated in skin prep solution. The prep solution prepares the skin prior to application of a dressing or bandage. When dry, the prep agent leaves a thin polymer film on the skin surface providing a clean surface for adhesion and a barrier to the natural body oils that can affect adhesion.

The IV extension tubing set, the Vital-Hold catheter stabilization device, the two foam tape strips and the APLICARE skin protectant prep pad will be integrated into one sterile unit blister package to provide the user with a "ready-to-use" set up avoiding the need to acquire/assemble components from various manufacturers.

STATEMENT OF INTENDED USE:

The IV extension tubing kits provide the user with a "ready-to-use" set up for the administration and withdrawal of fluids avoiding the need to acquire/assemble components from various manufacturers. The kits are indicated for one-time use.

The IV extension tubing set is indicated for use with a vascular access device for administration and withdrawal of fluids.

The Vital-Hold catheter stabilization device and the foam tape strips are indicated to provide a method for catheter securement.

The APLICARE skin prep pad is indicated to prepare the skin prior to application of a dressing or bandage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C/O Ms. Nanette Hedden
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085

APR - 5 2011

Re: K103551
Trade/Device Name: Intravenous Extension Tubing Kits
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 28, 2011
Received: March 1, 2011

Dear Ms. Hedden:

This letter corrects our substantially equivalent letter of March 25, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for D

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K103551

Device Name:

Intravenous Extension Tubing Kits

Indications for Use:

The IV extension tubing kits provide the user with a "ready-to-use" set up for the administration and withdrawal of fluids avoiding the need to acquire/assemble components from various manufacturers. The kits are indicated for one-time use.

The IV extension tubing set is indicated for use with a vascular access device for administration and withdrawal of fluids.

The Vital-Hold catheter stabilization device and the foam tape strips are indicated to provide a method for catheter securement.

The APLICARE skin prep pad is indicated to prepare the skin prior to application of a dressing or bandage.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R.L.C. Chen 3/24/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103551